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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/155,676	01/04/1999	DAVID WALLACH	WALLACH=21	8997

1444 7590 06/27/2003

BROWDY AND NEIMARK, P.L.L.C.  
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SUITE 300  
WASHINGTON, DC 20001-5303

EXAMINER
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EPPS, JANET L

ART UNIT	PAPER NUMBER
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1635

38

DATE MAILED: 06/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/155,676

Applicant(s)

WALLACH ET AL.

Examiner

Janet L. Epps-Ford, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 13-16, 20-22, 30, 43-50, 52-60 and 62-79 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 52-54 and 65-68 is/are allowed.
- 6) ☒ Claim(s) 13-16, 20-22, 30, 43-50, 55-60, 62-64 and 69-79 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## DETAILED ACTION

### *Response to Amendment*

1. The amendments to the claims filed on 4-15-03 does not comply with the requirements of 37 CFR 1.121(c) because the amendment, does not set forth the status of previously cancelled claim 61. Additionally, Applicants have amended claims 45-48, and 64 in the instant amendment. However, there are no markings to indicate the changes made to these claims. For example, Claims 45-48 and 64 were amended in the amendment filed 9-10-2001 to recite "a ligand capable of either inhibiting or increasing." However, instantly amended claims 45-48 and 64 recite "a ligand capable of either inhibiting or *decreasing*." In addition, Applicants do not indicate that claims 45-48 and 64 were currently amended.

### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 69, 13-16, 20-22, 30, 43-50, 54-60, 63-65, and 69-79 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

4. In the amendment filed 4-15-03, Applicants amended claim 69 to recite in part (c) "an amino acid sequence of a fragment of a) or b), which fragment binds to TRAF2 and either inhibits or increases the activity of NF- $\kappa$ B." It is noted that in prior versions of claim 69, the

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claim did not encompass “an amino acid sequence of a fragment” of (b), wherein (b) is “an amino acid sequence of an analog of a) having no more than ten changes in amino acid sequence of (a), wherein (a) recites “the amino acid sequence of SEQ ID NO: 2, an amino acid sequence encoded by the nucleotide sequence of SEQ ID NO: 6, or the amino acid sequence of SEQ ID NO: 5.” According to Applicants, the specification as originally filed, page 19, lines 21-24, provide support for wherein the invention encompasses “fragments” or “analogs.” However, contrary to Applicant’s assertions, this portion of the specification recites that the present invention concerns the “DNA sequences encoding biologically active TRAF-binding proteins, e.g. TRAF2-binding proteins, such as for example, NIK, as well as analogs, fragments and derivatives thereof.” It is clear from this passage that the analogs and fragments are directly referring to DNA sequences encoding biologically active TRAF-binding proteins. However, the specification as filed, does not describe with reasonable clarity, deliberateness, and precision, wherein the “fragments” recited in claim 69 encompass “fragments” of an “analog” having no more than ten changes in amino acid sequence of the amino acid sequence of SEQ ID NO: 2, an amino acid sequence encoded by the nucleotide sequence of SEQ ID NO: 6, or the amino acid sequence of SEQ ID NO: 5. In other words, there is no express support in the specification or claims as originally filed for Applicant’s current amendment to claim 69.

It is noted that all other claims, except claims 45 and 48, depend from claim 69. Claim 45 is drawn to a method for identifying and producing a ligand capable of either inhibiting or decreasing the cellular activity which is changed or mediated by TRAF2, wherein said method comprises screening for a ligand capable of binding to a polypeptide comprising at least a portion of TRAF2 having the amino acid residues 222-501 of TRAF2. Claim 48 recites a method

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for identifying and producing a molecule capable of directly or indirectly either inhibiting or decreasing the cellular activity which is changed or mediated by NIK, comprising screening for a molecule capable of either inhibiting or decreasing activities which is changed or mediated by NIK. In regards to the structural description of the polypeptides used in the claimed methods, as stated in the prior Office Action, the specification as filed provides no indication of what specific amino acid substitutions, deletions, insertions, or amino acid modifications must be made to the polypeptides of the instant invention in order to isolate those polypeptides with the claimed activity, specifically those which modulate NF- $\kappa$ B activity and bind TRAF2. It is apparent that further experimentation is necessary to isolate the compounds used in the instant claims, specifically to determine what amino acid substitutions, deletions, and/or insertions are necessary to isolate the polypeptides encompassed by the present invention. Moreover, the specification as filed does not sufficiently describe the DNA sequence fragments that are capable of encoding a polypeptide that binds to TRAF2 and either inhibits or increases the activity of NF- $\kappa$ B. Additionally, in regards to the DNA molecules that hybridize under moderately stringent conditions, such that said molecule encodes a polypeptide that is capable of encoding a polypeptide that binds to TRAF2 and either inhibits or increases the activity of NF- $\kappa$ B, Applicants have merely described the instant application by means of describing the method of isolating said sequences.

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5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 45-48 and 64 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 45-48 and 64 recite the phrase "a ligand capable of either inhibiting or decreasing," this phrase is vague and indefinite since the terms "inhibiting" and "decreasing" are not mutually exclusive, therefore it is unclear how a ligand can be capable of either inhibiting or decreasing at given point.

#### *Conclusion*

7. Claims 52-54, and 65-68 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

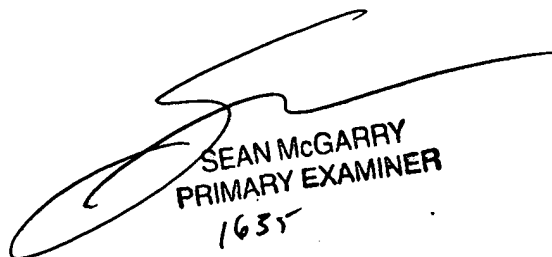
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford, Ph.D. whose telephone number is 703-308-8883. The examiner can normally be reached on M-T, Thurs-Fri, 8:30AM-6: 30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 703-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-746-5143 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Janet L. Epps-Ford, Ph.D.  
Examiner  
Art Unit 1635

*JLE*  
June 25, 2003

  
SEAN MCGARRY  
PRIMARY EXAMINER  
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